

### **REMARKS**

Applicants have received and carefully reviewed the Office Action mailed July 19, 2007. Claims 18, 27, and 33 have been amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Reconsideration and withdrawal of the rejections are respectfully requested.

### **Rejection under 35 U.S.C. § 103(a)**

Claims 18-22, 26, 27, 31-35, and 46-48 are rejected as being unpatentable over Foley (US 5,792,044) in view of Ash (WO 83/03189). Independent claim 18, as amended, recites:

18. (Currently Amended) A system for performing a fixation procedure at a spinal location within a patient, comprising:  
at least two fasteners adapted to be fixed to two adjacent vertebrae;  
an elongate body having a proximal end and a distal end and defining a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location, the elongate body including a passage extending between the proximal and distal ends sized to permit passage of the at least two fasteners therethrough; and  
a fixation element sized to pass through the passage of the elongate body and configured to engage the at least two fasteners;  
wherein the elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; wherein the cross-sectional area of said passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae.

Independent claims 27 and 33 recite similar cross-sectional areas of the passage. Neither Foley nor Ash appears to teach or suggest such a structure. The Examiner acknowledges that Foley fails to disclose a system comprising an elongate body that is expandable at the distal end at a first location. In the body of the rejection over Foley, Ash, and Zdeblick, the Examiner further acknowledges that Foley modified by Ash fail to disclose a system with at least two fasteners capable of being passed through the passage of an elongate element. The Examiner has thus acknowledged that neither Foley nor Ash teach each element of the claims. It appears the Examiner has not considered the element added in the previous response, the fixation element

sized to pass through the passage of the elongate body and configured to engage the at least two fasteners. Neither Foley nor Ash appear to teach such an element. Further, there is no motivation for one of ordinary skill in the art to modify the devices of Foley or Ash to achieve such a structure. Additionally, neither Foley nor Ash appear to teach or suggest an access device having a cross-sectional area of a passage at a first location sized to permit visualization of two fasteners fixed to two adjacent vertebrae. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 18-23, 25-27, 30-36, 38-41, and 46-48 are rejected as being unpatentable over Foley in view of Ash and further in view of Zdeblick (US 6,206,922). Independent claims 18, 27, and 33 have been amended to recite the access device, in the second (expanded) configuration, has a passage cross-sectional area sized to permit visualization of two fasteners in two adjacent vertebrae. None of Foley, Ash, or Zdeblick appear to teach or suggest the systems as now claimed.

The Examiner acknowledges that Foley fails to disclose a system comprising an elongate body that is expandable at the distal end. The Examiner further acknowledges that Foley modified by Ash fail to disclose a fixation element with at least two fasteners capable of being passed through the passage of an elongate element. The Examiner then asserts that Zdeblick teaches a system comprising a fixation element capable of being passed through the passage of an elongate element in order to fuse two adjacent vertebrae, and it would have been obvious to one of ordinary skill in the art to include the fixation element of Zdeblick in the system of Foley as modified by Ash in order to fuse two adjacent vertebrae.

Zdeblick does not appear to teach an expandable access device having a passage that, when the device is in an expanded configuration, has a cross-sectional area sized to permit visualization of two fasteners fixed to two adjacent vertebrae, as is recited in the claims. Zdeblick appears to teach a sleeve 76 that functions as a fixed diameter working channel through which a fusion device 10 is implanted using an implant driver 50. See column 11, lines 8-17 and FIG. 11c. Zdeblick does not appear to teach the sleeve 76 as being expandable or being sized to permit visualization of two fasteners fixed to two adjacent vertebrae, as is recited in the claims. While Zdeblick does teach passing an implant through the fixed diameter sleeve 76, Zdeblick does not appear to teach or suggest the sleeve 76 is configured for passing fasteners through it.

Zdeblick teaches the fusion device as having offset screw bores 267 and teaches the longitudinal axes of the two screw bores intersect outside the hollow body 251 and the end wall 256. See column 10, lines 2-9 and FIG. 10. Comparing the positioning of the screws relative to the implant in FIG. 10 with the fixed diameter sleeve 76 and implant in FIG. 11c, one of ordinary skill in the art would understand that the sleeve 76 of Zdeblick is not structured to have a cross-sectional area sized to permit visualization of two fasteners fixed to two adjacent vertebrae, as is recited in the claims.

Ash does not appear to teach a device that, when expanded, is structured to permit visualization of two fasteners fixed to two adjacent vertebrae. Further, there is no motivation for one of ordinary skill in the art to modify the devices of Foley, Ash, or Zdeblick to achieve the structure of the expandable access device as claimed. Reconsideration and withdrawal of the rejection are respectfully requested.

Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully submitted,  
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By their Attorney,

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